

Boost to the gynecology area

REIG JOFRE AWARDED FOR THE "PROMOTION OF BIOMEDICAL R & D + i" BY THE RESEARCH THAT LED TO GynEC[®]-DX, AND IT KEEPS WORKING TO EXPAND ITS DIAGNOSIS SCOPE

- Reig Jofre has been recognized by the research that led to GynEC[®]-DX, first molecular diagnostic test for early detection of endometrial cancer, with the prize to the **promotion of biomedical R & D + i** awarded by the magazine *New Medical Economics*.
- This award coincides with the presentation of the **2016 Oncology Guide for Endometrial Cancer by SEGO**, which for the first time it mentions the higher effectiveness of GynEC[®]-DX versus conventional diagnostic techniques.
- **GynEC[®]-DX**, own development of Reig Jofre's R&D team, is the first diagnostic kit in the world based on the identification of biomarkers, which has been the subject of several national and international publications, as well as a first PhD thesis.
- Currently, Reig Jofre works in the **PredictGyn** project for this medical device to be able to diagnose endometrial cancer in addition to predict the aggressiveness of the tumor.

Barcelona (Spain), November 4, 2016. The pharmaceutical company Reig Jofre received yesterday the prize to the **Promotion of biomedical R & D + i**, awarded by *New Medical Economics*, leading magazine in health management content, by the research that led to the development of GynEC[®]-DX, the first *in vitro* test for molecular diagnosis marketed in the world for early detection of endometrial cancer, based on the identification of biomarkers in endometrial aspiration.

This award recognizes the contribution of Reig Jofre's R&D team to the development of biomedicine and health sciences in Spain through an innovative research on the management and care to patients.



This award also coincided with the presentation yesterday of the **2016 Oncology Guide for Endometrial Cancer by SEGO**, at the National Conference of the Oncology Section of the Spanish Society of Gynecology and Obstetrics (SEGO), which for the first time mentioned not only the availability of GynEC[®]-DX diagnostic kit based on the gene expression of biomarkers, but also that its effectiveness appears to be superior to conventional techniques (such as the endometrial aspiration or the biopsy directed by hysteroscopy) for diagnosing endometrial cancer.

Endometrial cancer is the most common female genital neoplasia. Survival in early stages exceeds 95%. Current diagnostic methods such as endometrial aspiration or biopsy guided by hysteroscopy does not have 100% sensitivity and are not exempt from potential complications for patients. In addition, the rate of insufficient samples in endometrial aspiration reaches 30% and the overall rate of failure in obtaining a diagnosis can exceed 40%.

Unlike conventional methods, the molecular diagnostic test GynEC[®]-Dx, requires a smaller amount of sample than the requested in a histological diagnosis, it allows a rapid and early diagnosis of endometrial carcinoma at the doctor's office, and it establishes also a positive or negative result in about 90% of the patients.

In words of the program coordinator of the SEGO oncology guide, Dr. Jordi Ponce i Sebastia, Head of Gynecology at the University Hospital of Bellvitge and Chair of the Spanish Society of Gynecologic Oncology of SEGO: *"The biomolecular gene technique should not be considered as invasive, since no more than an endometrial aspiration is required (a sample of endometrial tissue from the uterine cavity obtained through a cannula). And on the other hand, it is a rapid technique (only 24 hours for diagnosis) and very easy to incorporate into exploration and routine gynecological screening test."*

According to Dr. Ponce: *"The applicability of this fast and reliable test, called GynEC[®]-DX, improves the diagnostic accuracy of conventional tests of aspiration or biopsy by hysteroscopy, minimizing the possibility of inconclusive results, and provides high-value information in specific clinical profiles, which reinforces physician confidence in the decision-making process in the early diagnosis of endometrial cancer. Its high negative predictive value, can avoid invasive diagnostic methods in large numbers of patients and could even result in savings for the public health system."*

Similarly, Dr. Ponce announced the forthcoming publication of a pharmacoeconomic study that may objectify the savings scale, this project has been conducted by the management area of Bellvitge Hospital together with its reference areas of primary care. In this sense, it is planned the publication of a monograph



on the applicability of GynEC[®]-DX in certain clinical profiles, prevalent and with real impact where the information GynEC[®]-DX provides is of high value to reinforce the physicians' diagnostic or therapeutic decision-making.

GynEC[®]-DX, which was introduced in hospital pharmacies in 2014 for the inclusion into its medical protocols, is currently used successfully in more than a dozen hospitals and private clinics in Spain, for the diagnosis of endometrial cancer in suspected patients.

In May, this year, Reig Jofre announced the acquisition of 50% of Geadic Biotech, becoming the sole shareholder of the biotech company holder of GynEC[®]-DX, of which it already owned the other 50%.

Reig Jofre contributed to the development of GynEC[®]-DX since its start in 2006, when the project was launched and developed jointly in the early years with Oryzon Genomics. Since 2013 Reig Jofre leads the development work around this medical device, which has been the subject of numerous national and international publications in collaboration with the most prestigious Spanish centers in the research of endometrial cancer, as well as the publication of the first PhD thesis on the accuracy of GynEC[®]-DX, whose results confirmed that those samples obtained by aspiration in which the pathologist could not get a conclusive result, GynEC[®]-Dx determined an outcome in 88% of cases.

Currently, Reig Jofre's R&D team works on the project **PredictGyn** (<http://www.reigjofre.com/en/r-d/joint-projects>) for this medical device to be able to indicate not only the diagnosis of endometrial cancer in both symptomatic and asymptomatic women with abnormal endometrium, but also the aggressiveness of the tumor.

In addition, Reig Jofre, together with Hospital La Paz in Madrid, is working in a study to promote the use of GynEC[®]-DX in monitoring patients with Lynch syndrome or hereditary non-polyposis colorectal cancer, because of their genetic predisposition to developing both cancers.

Reig Jofre expects to position GynEC[®]-DX as the fastest, most reliable and less invasive diagnostic test for early detection of endometrial cancer, by improving the diagnostic accuracy of conventional tests and providing the necessary information to reinforce physician confidence in the decision-making in the process of screening of endometrial cancer. At the same time, Reig Jofre is working on an internationalization plan for marketing this development into markets where the company has a significant presence.



Receive Reig Jofre's news by registering in the company's **subscription center** of the new corporate website: **www.reigjofre.com**

About Reig Jofre

After the merger between Laboratorio Reig Jofre and Natraceutical, the new Reig Jofre is a pharmaceutical company whose business is divided into two major areas: one main for the marketing and manufacture of own developments (RJF Pharma, approximately 79% of sales in 2015) and one of specialized contract development and manufacturing (RJF CDMO, 21% of sales in 2015). At its core activity, the company focuses on the development of technological-specialization products (beta-lactam antibiotics, injectable and freeze-dried products); therapeutic-specialization products in the areas of dermatology, respiratory/ENT and gynaecology; and food supplements and consumer healthcare. The company directs its R&D to develop new indications and/or dosage forms of already-known active ingredients, generic medicines with a special focus on the development of injectable, freeze-dried and generic beta-lactam antibiotics, topical dermatological products, OTCs and food supplements as well as the development of new innovative molecules in partnership with start-ups and biotech research centres.

Reig Jofre trades on the Spanish stock exchange under the ticker RJF.
Share capital: 63,214,220 shares.

For further information

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